510(k) SUMMARY

OCT 2 9 2010

Date of Summary October 21, 2010

Product Name Bio-Rad MRSA*Select* -- Wound Specimens
A selective and differential chromogenic medium for the qualitative detection of methicillin-resistant *Staphylococcus aureus* from skin and soft-tissue wound specimens. Results can be interpreted after 18 - 28 hours incubation.

Sponsor
Bio-Rad
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Correspondent
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Substantially Equivalent Device

MRSA*Select* for skin and soft-tissue wounds is substantially equivalent to Bio-Rad MRSA*Select* – extended incubation (reference 510(k) K081212). Products are the same chromogenic media used for the detection of MRSA direct from a specimen swab.

Manufacturer: Bio-Rad
Product: MRSA*Select* -- extended incubation

Similarities

Product Attribute	Bio-Rad MRSA*Select*™ Extended Incubation	Bio-Rad MRSA*Select*™ Wound Specimen
Intended use	MRSA*Select* is a selective and differential chromogenic medium for the qualitative detection of MRSA direct from a nasal swab for the detection of methicillin resistant *Staphylococcus aureus* (MRSA).	**MRSA***Select* is a selective and differential chromogenic chromogenic medium for the qualitative detection of methicillin resistant *Staphylococcus aureus* (MRSA) from skin and soft-tissue wound specimens.
Product format	Chromogenic agar	Chromogenic Agar
Read time	After 18-24 hour incubation	After 18-24 hours incubation
Quality Control	Daily with recommended	Daily – same recommended organisms

	organisms	

Differences

Product Attribute	Bio-Rad MRSA*Select*™ Extended Incubation	Bio-Rad MRSA*Select*™ Wound Specimen
Intended use	MRSA*Select* is a screen for the detection of colonization of methicillin resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings.	**MRSA***Select* is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA***Select*™ is not intended to guide, or monitor treatment for MRSA infection, or provides results of susceptibility to methicillin.

Product Description

Methicillin-resistant *Staphylococcus aureus* is a major cause of nosocomial and life threatening infections which have been associated with significantly higher rates of mortality and morbidity. The Bio-Rad MRSA*Select* is a selective and differential chromogenic culture medium for the qualitative detection of MRSA from skin or soft-tissue wound specimens. Results can be interpreted after 18 - 28 hours incubation.

Intended Use

MRSA*Select*™ is a selective and differential chromogenic medium for the qualitative detection of methicillin resistant *Staphylococcus aureus* (MRSA) from skin and soft-tissue wound specimens. The **MRSA***Select*™ is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA***Select*™ is not intended to guide, or monitor treatment for MRSA infection, or provides results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.

Summary of Technology

MRSA*Select* is a selective and differential chromogenic medium for the qualitative detection of methicillin resistant *Staphylocccus aureus* (MRSA) from skin and soft-tissue wound specimens. The selectivity of this medium is based on the presence of an antibiotic/antifungal mixture and an optimized salt concentration that inhibits the growth of yeast and the majority of Gram negative and Gram positive bacteria with the exception of methicillin-resistant staphylococci. Identification is based on the cleavage of a chromogenic substrate by a specific enzymatic activity of *Staphylococcus aureus* leading to a strong

pink coloration of the *Staphylococcus aureus* colonies.

Within 18 – 28 hours incubation time methicillin-resistant *Staphylococcus aureus* produce small pink colonies on MRSA*Select*. Coagulase negative methicillin-resistant staphylococci that do not metabolize the chromogenic substrate appear as colorless or white colonies (possibly light pink). Methicillin sensitive staphylococci (MSS) are inhibited.

Performance Data

Interfering Substances
In order to evaluate the possible interference of common topical agents used in wound care samples of these agents were inoculated with MRSA and plated on MRSA*Select* media.
Use of the following compounds has an inhibitory effect on MRSA growth that is unrelated to medium performance:

Bactine (Benzalkonium chloride 0.13%, Lidocaine hydrochloride 2.5%); Betadine (liquid) (Povidone-iodine 10%), Iodine Tincture (liquid) (Iodine 2%), Biseptine (liquid) (Chlorhexidine Gluconate 0.25%, Benzalkonium chloride 0.025%), Sodium hypochlorite (liquid), StaphAseptic (ointment) (Benzethonium Chloride 0.2%, Lidocaine HCl 2.5%), and silver chloride.

Cross Reactivity Testing (Analytical Specificity)
To evaluate the analytical specificity of the **MRSA***Select*™ media 35 bacterial and fungal strains found in wound or skin samples were cultured and inoculated onto **MRSA***Select*™ plates at a concentration of $\geq 10^6$ CFU/mL.

No cross-reactivity was observed on any strains tested. Most strains showed no growth on **MRSA***Select*™ with the exception of *Corynebacterium jeikeium* and *Candida tropicalis*. With both of these organisms pinpoint white colonies were observed; these are not representative of MRSA colonies, and therefore these are not cross-reactants. No variation was seen between 24 and 28 hour incubation time.

Analytical Sensitivity To evaluate the analytical sensitivity of the **MRSA***Select*™, 102 strains of MRSA, including USA100, 200, 300, 500, 600, 700, 800, and 1000 were inoculated onto **MRSA***Select*™ plates at concentrations of 10^3 to 10^4 CFU/mL. USA300-0114 was also tested. 97% (99/102) sensitivity was observed after 24 hours incubation.

Reproducibility
A panel of 6 organisms, including MRSA, MSSA and *S. epidermidis,* was evaluated on **MRSA***Select*™. It was performed at concentrations of 10^6 CFU/mL for MRSA, and 10^8 CFU/mL for non-MRSA. The panel was tested in triplicate each day for three days at three clinical sites. Overall reproducibility was 100% after 24 hours incubation when testing this panel.

Method Comparison

943 skin and soft-tissue wound samples were collected and tested at four clinical laboratories in the United States. Each sample was tested on **MRSA***Select*™, Trypticase Soy Agar (TSA) with 5% Sheep's Blood, and Tryptic Soy Broth (TSB) with 6.5% NaCl. Samples that were positive on TSA or TSB were confirmed with Gram stain, Pastorex™ Staph Plus, and *mecA* mediated oxacillin resistance using 30 µg/mL Cefoxitin disk (R: ≤21 mm, S: ≥ 22 mm)

The following results were obtained: specificity 99.4% (95% CI: [98.5, 99.8]) and sensitivity 91.7% (95% CI: [87.3, 94.7]). The overall prevalence of MRSA in the study was 24.2% (95% CI: [21.5, 27.0]).

MRSASelect™ vs. Routine Culture and TSB

		Routine Culture &TSB		
		Pos	**neg**	**total**
MRSA *Select*™	**pos**	209	4	213
	neg	19*	711	730
	total	228	715	943

* For 12/19 samples – MRSA were isolated only from TSB with 6.5% NaCl and were not isolated on initial direct culture.

Specificity	99.4% [98.5, 99.8]	Overall % agreement	97.6% [96.3, 98.4]
Sensitivity	91.7% [87.3, 94.7]		

Statement of Safety and Efficacy

The data presented demonstrates the safety and efficacy of the Bio-Rad MRSA*Select*™ as compared to routine culture and identification when results are interpreted after 18 to 28 hours incubation in ambient air.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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Attn: Fran White

OCT 29 2010

Re: K100589
Trade/Device Name: **MRSA***Select*
Regulation Number: 21 CFR §866.1700
Regulation Name: Culture medium for antimicrobial susceptibility tests.
Regulatory Class: Class II
Product Code: JSO
Dated: October 21, 2010
Received: October 25, 2010

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100589

OCT 2 9 2010

Device Name: MRSA*Select*

Indications for Use:

MRSA*Select*™ is a selective and differential chromogenic medium for the qualitative detection of methicillin resistant *Staphylococcus aureus* (MRSA) from skin and soft-tissue wound specimens. The **MRSA***Select*™ is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA***Select*™ is not intended to guide, or monitor treatment for MRSA infection, or provides results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100589